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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,529	03/01/2000	NICHOLAS P. HARBERD	620-91	2031

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NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/17/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/485,529

Applicant(s)
HARBERD et al

Examiner
Medina Ibrahim

Art Unit
1638



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 7, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6, 10-15, 17-29, 32-46, and 48-50 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3-5, 32-43, and 46 is/are allowed.
- 6) ☒ Claim(s) 6, 14, 15, 17-19, 21-24, 44, 45, 48, and 49 is/are rejected.
- 7) ☒ Claim(s) 10-13, 20, 25-29, and 50 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 04/07/03 in reply to the Office action mailed 11/05/2002 and amendment F have been entered. Claims 1, 3-6, 10-15, 17-29, 32-46 and 48-50 are pending and are under examination.

All previous rejections and objections not stated below have been withdrawn.

Claim Rejections - 35 USC § 112, 2nd paragraph

Claims 17 and 44-45 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is indefinite because it is unclear if the deleted amino acid sequence of SEQ ID NO:103 is in addition to the sequence of SEQ ID NO:104 deleted in parent claim 15, as stated in the last Office action. Applicant has not responded to the rejection.

Claim 44 is indefinite because "the isolated plant" lacks antecedent basis. Dependent claim 45 is included in the rejection.

Claim Rejections - 35 USC § 112, 1st paragraph

Claims 6, 14-15, 17-19, 21-24 and 48-49 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated polynucleotide sequences from *Triticum aestivum* encoding a polypeptide comprising

SEQ ID NO:104 , polynucleotides of SEQ ID NO:12, 14-15 encoding of the polypeptide sequences 5, 7-8 or with specified partial amino acid sequences deleted and having GA-unresponsive dwarfing activity, and method of transforming a plant cell with said polynucleotide, transformed plant cell, plant and seed, does not reasonably provide enablement for any isolated polynucleotide which specifically hybridizes under particular hybridization conditions to SEQ ID NO:14 and encoding a polypeptide that retains dwarfing or GA-unresponsive activity or wherein the polypeptide has any one or more amino acids deleted, and a method for producing said polynucleotide. This rejection is repeated for the reasons of record as set forth in the Office action mailed 11/05/2002. Applicant's arguments filed 04/07/03 have been considered but are not deemed persuasive.

Applicant's argue that the instantly claimed invention is enabled based on the analysis of *In re Wands*. Applicant relies upon the following points in support of this position. 1) the claimed genus of the nucleic acids is defined by a close structural relationship to SEQ ID NO:14 and by function. Applicant asserts that SEQ ID NO:14 defines and limits the structure of all members of the genus. 2) residues conserved in the polypeptide of the invention and motifs necessary for function or GA responsiveness are disclosed. 3) Because of the high stringency conditions recited in the claims, one would expect that most if not all hybridizing sequences will have the stated function. Applicant asserts that amount of experimentation required to test these sequences is not undue. Applicant finally asserts that, given the ample guidance

provided in the specification, the disclosed variants and homologue, and the working examples, claims 6, 14-15, 17-19, 21-24, and 48-49 are enabled.

Applicant's arguments have been considered but are not persuasive for the following reasons: 1) while the claimed nucleic acids share close structural relationship with SEQ ID NO:14, and while SEQ ID NO:14 has both the claimed structural and functional limitations, Applicant has provided no scientific evidence to support the conclusion that most if not all hybridizing sequences will have the stated activity. Hybridization conditions describe the conditions and parameters that particular sequences will hybridize to each other, one skilled in the art will have to test all the resultant nucleic acids for activity because one cannot predict function based on close structural relatedness only. 2) Lazar et al and Broun are relied upon because both articles provide unpredictability in determining function based on close structural relationship. Lazar teaches that the conservative substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor-alpha while non-conservative substitutions with alanine or asparagine had no effect. One skilled in the art would not expect that modifications that involve conservative substitution of amino acids are likely to change protein biological activity, while substitutions that are less conservative are unlikely to affect protein function. 3) while the instant specification provides ample guidance on conserved regions of the polypeptide of the inventions as shown in Figure 10, guidance on motifs required for GA-responsive activity, homologue and variants from related species, and guidance on

deletion of specific residues with known function, the specification does not provide guidance regarding deletions of "anyone or more amino acids" that retain the polypeptide function. It is unpredictable how the "anyone or more amino acid deletion" will affect the stated polypeptide activity. 4) the rejected claims are not limited to the disclosed homologue or variants of related plant species, but encompass polynucleotide encoding a polypeptide comprising SEQ ID NO:104, wherein SEQ ID NO:104 is a partial sequence with only 14 contiguous amino acids. Note claims 48-49, drawn to a method for identifying the polynucleotide of claim 6 are also included in the rejection (see also paragraph bridging pages 4 and 5 of the Office action of 11/05/2002 where it states the rejection to claim 48). The claims were inadvertently indicated allowable in the last Office action.

Therefore, for the reasons indicated above and in previous Office actions, claims 6, 14-15, 17-19, 21-24, and 48-49, drawn to hybridizing polynucleotide sequences encoding a polypeptide having the stated function or a method for producing said polynucleotides, and polynucleotide sequences encoding polypeptides having one or more amino acids deleted while retaining the stated function are not supported by enabling disclosure. The rejection is maintained.

Written Description

Claims 6, 14-15, 17-19, and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the Office action mailed 11/05/2002. Applicant's arguments filed 04/07/03 have been considered but are not deemed persuasive.

Applicant's arguments are basically the following: Because of the high stringency conditions and the requirement that the nucleic acids encode a polypeptide having the stated activity as recited in the claims, and the representative number of species disclosed, one would know Applicant was in possession of the claimed invention at the time of filing. Therefore, Applicant asserts that the written description requirement is met. Applicant urges that the rejection be withdrawn.

These arguments are not persuasive for the reasons of record. Hybridizing property or structural similarity of nucleic acids cannot be used to predict the functional activity of the nucleic acids, as stated in the last Office action. In addition, the rejected claims are not limited to the disclosed homologue or variants of related plant species, but encompass polynucleotide encoding polypeptides comprising SEQ ID NO:104, wherein SEQ ID NO:104 is a partial sequence with only 14 contiguous amino acids. One skilled in the art would expect a substantial variation in structures among polynucleotide encoding polypeptides that share only 14 contiguous amino acids. The rejection is maintained.

Remarks

Claims 1-6, 10-15, 17-29, and 32-46 and 48-50 are deemed free of the prior art.

Claims 1, 3-5 and 32-43, and 46 are allowable.

Claims 10-13, 20, 25-29 and 50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703)

306-5822. The Examiner can normally be reached Monday -Thursday from 8:30 AM to 5:00 PM and every other Friday from 9:00AM-5:30PM .

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

June 12, 2003

mai


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600